



**TO:** The Honorable Candice S. Miller, Chair  
The Honorable Stephen F. Lynch, Ranking Member  
Committee on Government Reform, Subcommittee on Regulatory Affairs

**FROM:** The American Cancer Society  
Presented by Dr. Janet L. Abraham, Dana Farber Cancer Institute

**DATE:** September 13, 2005

**SUBJECT:** **Addressing the issue of Schedule II prescription pain medications -  
their use and abuse**

The American Cancer Society is the nationwide community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer, through research, education, advocacy, and service. A priority of the American Cancer Society is to ensure adequate pain and symptom control -- essential elements to improve the quality of life for cancer patients. Pain is a major health problem in the United States, especially the kind of pain that is often experienced by individuals with cancer.

Up to 70 percent of cancer patients experience uncontrolled pain at some point during their illness, depending on the stage of the disease.<sup>12</sup> Further research indicates that nearly half of advanced cancer patients with pain do not get adequate relief of their pain in spite of the fact that medications and other therapies currently exist to relieve almost all cancer pain. The American Cancer Society believes that our nation must strive to protect and encourage legitimate pain treatment, while addressing the real dangers of prescription drug diversion and abuse. The Society strongly supports a balanced policy toward the regulation of pain medications that are also controlled substances. The Society also supports appropriate law enforcement actions to ensure that controlled substances, including pain medications, are used only in the course of legitimate medical practice. However, the Society strongly opposes efforts to limit the distribution or availability of pain medication to the patients who need them. While we agree that opioid medications should be kept out of illegal or improper hands, the Society opposes law enforcement activities that have unintended, but harmful effects on people with pain. We commend members of the Subcommittee for their leadership in searching for solutions to protect our nation from the devastating effects of prescription drug abuse. However, the American Cancer Society opposes activities that threaten to roll back hard-won progress that has expanded the use of opioids as a viable option for treating pain. Those with legitimate needs should not be made to suffer as a result of the actions of those who violate the law.

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<sup>1</sup> Foley KM. The treatment of cancer pain. *New Engl J Med* 1985;313:84-95.

<sup>2</sup> Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. *New Engl J Med* 1994;330:592-6.

The fear of regulatory scrutiny is one of the barriers that inhibits healthcare provider treatment of cancer patients' pain – particularly in cases involving medications such as opioids that have been known to draw the attention of law enforcement and regulatory officials.<sup>3</sup> While federal law permits the appropriate use of opioids for pain management in patients, fear of controlled substances and the agencies that enforce the laws governing them contribute to inadequate treatment of cancer pain. Increasing media reports describing abuse and diversion of opioid pain medications have also heightened patient and provider awareness of the regulatory scrutiny surrounding prescription of these medications. Stigma associated with prescribing these medications may increase patient fear of addiction<sup>4</sup> and may cause providers to choose lower profile and potentially less effective medications.

Misperceptions and misinformation about the risk of addiction to certain pain medications can lead patients and physicians to avoid the most effective methods of pain control. Cancer patients who take opioid medications to treat their pain are *not* drug addicts. In fact, opioid addiction among all pain patients is rare,<sup>5</sup> and appropriate cancer pain management does not result in addiction.<sup>6</sup> Addiction, tolerance, and physical dependence should *not* be confused.

- *Addiction* is characterized by psychological dependence. As defined by the American Medical Association, addiction is “the compulsive use of a substance resulting in physical, psychological or social harm to the user and continued use despite that harm.”<sup>7</sup>
- *Tolerance* is when a drug no longer works to keep pain away or when a higher dosage of a drug is needed to treat pain.<sup>8</sup>
- *Physical dependence* describes the experience of withdrawal symptoms in some patients who stop taking pain medications – especially if stopped abruptly. The World Health Organization Expert Committee on Drug Dependence has stated that cancer patients who exhibit signs of physical dependence (i.e., show withdrawal symptoms) cannot be defined as drug dependent.<sup>9</sup> In addition, side effects associated with stopping some pain medications can be avoided by gradually tapering dose when the medication is no longer needed.

The American Cancer Society recognizes there is an important need to improve the quality and increase the use of adequate cancer pain treatment. The Society also recognizes and supports the strong societal interest in assuring the appropriate use of controlled substances. We recognize that diversion of opioids does occur and should be

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<sup>3</sup> Von Roenn JH, Cleeland CS, Gonin R, Hatfield AK, Pandya KJ. Physician attitudes and practice in cancer pain management: A survey from the Eastern Cooperative Oncology Group. *Ann Intern Med* 1993;119:121-6.

<sup>4</sup> Jacox A, Carr DB, Payne R, et al. Management of cancer pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, MD: Agency for Health Care Policy and Research, U.S. Department of Health and Human Services, Public Health Service; 1994.

<sup>5</sup> Joranson DE. “Current thoughts on opioid analgesics and addiction.” *Symptom Control in Cancer Patients* (Japan) 1995. 6(1): 105-110. Available via the Internet at: <http://www.medsch.wisc.edu/painpolicy/publicat/95sccp.htm>

<sup>6</sup> Joranson DE, Ryan KM, Gilson AM, Dahl JL. Trends in medical use and abuse of opioid analgesics. *JAMA* 2000;283:1710-14.

<sup>7</sup> CancerCare. “Managing your cancer.” Available via the Internet at: [http://www.cancer.org/managing/pain/pain\\_17964.asp](http://www.cancer.org/managing/pain/pain_17964.asp)

<sup>8</sup> *Ibid.*

<sup>9</sup> Joranson DE. “Current thoughts on opioid analgesics and addiction.” *Symptom Control in Cancer Patients* (Japan) 1995. 6(1): 105-110. Available via the Internet at: <http://www.medsch.wisc.edu/painpolicy/publicat/95sccp.htm>

addressed. However, we are greatly concerned that attention to the misuse of controlled substances has overshadowed and impeded attempts to manage pain. Currently, our nation has not found a proper balance between these two issues and the cost has been at the expense of those who need their pain controlled. The Society believes that concern for cancer pain management should receive equal focus and comparable resources from governments and their agencies at all levels. Doctors, nurses and pharmacists must continue to be held responsible for improper prescribing. However, legislative and regulatory efforts must be focused on the primary sources of the problem, such as pharmacy thefts, forgery, and diversion operations. Abuse and diversion of prescription drugs should be addressed directly without interfering with patients' access to essential treatments and without debilitating legitimate medical practices.

The American Cancer Society strongly supports the primacy of clinical decision-making between patients and health care providers and opposes any efforts that might have an adverse effect on health care providers' willingness and ability to provide pain medication and pain management when treating patients with cancer and other chronic pain. The Society encourages the drug enforcement community to work with the health care community and patient advocates to develop a balanced policy toward controlled substances. A part of this effort should include educating health care providers and patients about the laws and regulations controlling the distribution, prescribing, and dispensing of these critical medications. Towards that end, the American Cancer Society joined 20 other health organizations and the Drug Enforcement Agency by issuing a joint policy statement concerning the "principle of balance" in strategies to promote pain relief while preventing abuse of pain medications. According to this joint policy statement (Appendix A), efforts to curb the abuse and diversion of prescription medications should not negatively impact patients' access to appropriate pain management treatment options.

Building state consensus on quality pain management, decreasing barriers to effective pain management, and developing balanced policies to pain management is also critical. This may include adoption of the Federation of State Medical Boards "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" (Appendix B) in all 50 states, and may also include a consensus policy statement by members of the licensing boards representing all state health care providers. The development of a state advisory council on pain management may also be a proactive solution to improve pain management and to bring together clinicians, policy makers, patient advocates, and drug and law enforcement officials.

The American Cancer Society supports efforts to prevent the abuse and misuse of opioid analgesics and stands ready to work with federal, state and local officials to find avenues to address escalating abuse problems without contributing to the already gross under-treatment of pain.

For cancer patients and thousands of others who suffer from persistent pain, sustained release opioids and other opioid analgesics are often the only effective and efficient treatment options. When used for legitimate medical purposes, these medications can

dramatically improve the quality of life for cancer patients and millions of other Americans who would otherwise be forced to live their lives in unbearable, chronic pain.

Thank you for the opportunity to give cancer patients a voice concerning the Subcommittee's efforts to assess the regulation of Schedule II prescription medications.